

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference sankyoFP0413	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/006093	International filing date (day/month/year) 27.04.2004	Priority date (day/month/year) 28.04.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant SANKYO COMPANY, LIMITED		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.
3.	This report is also accompanied by ANNEXES, comprising: <ul style="list-style-type: none"> a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4.	This report contains indications relating to the following items: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/006093

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (Rule 12.3 and 23.1(b))
☐ publication of the international application (Rule 12.4)
☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 13-25

because:

☒ the said international application, or the said claims Nos. 13-25
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 13-25 pertain to treatment of the human
body by therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 13-25

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished
☐ does not comply with the standard

the computer readable form ☐ has not been furnished
☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
1. Statement	
Novelty (N)	Claims 1-6 YES Claims 7-12 NO
Inventive step (IS)	Claims YES Claims 1-12 NO
Industrial applicability (IA)	Claims 1-12 YES Claims NO
2. Citations and explanations (Rule 70.7)	
	Documents cited in the international search report:
	Document 1: JP 4-282324 A
	Document 2: JP 2002-536332 A
	Document 3: JP 2001-294526 A
	Document 4: WO 02/30425 A1
	Document 5: WO 01/76573 A2
	Document 6: Toru KOMAI, Bio. Clin. Vol. 17, No. 10, pages 918-923, 10 September 2002
	Document 7: SI McFarlane et al., J. Clin. Endocrinol. Metab. April 2002, 87(4), pages 1451-8
	Document 8: DJ Freeman et al., Circulation, January 23 2001, 103(3), pages 357-62
	Document 9: L. Mangaloglu et al, Metabolism, April 2002, 51(4), pages 409-18
	Document 10: BY Cingozbay et al., J. Int. Med. Res., Jan-Feb 2002, 30(1), pages 21-5
	Document 11: G Paolisso et al., Atherosclerosis, May 2000, 150 (1), pages 121-7
	Document 12: AS Dumont et al., J Neurosurg, Sep 2001, 95(3), pages 466-71
	Document 13: H. Usui et al., Nephrol. Dial. Transplant., Feb 2003, 18(2), pages 265-72
	Document 14: JR Sowers, Am. J. Cardiol. Feb 20, 91(4A),

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

pages 14B-22B

Claims 7-12

Documents 1-5, 7, and 12-14 disclose the application of HMG-CoA reductase inhibitors in the prevention and treatment of diabetes and diabetic complications. Therefore, these claims lack novelty and do not involve an inventive step.

Claims 1-12

Documents 6 and 7 disclose a relationship between HMG-CoA reductase inhibitors and saccharometabolism. Therefore, a person skilled in the art would easily be able to investigate the effects of each type of HMG-CoA reductase inhibitor on saccharometabolism based on the disclosures in each document. Hence, the claims do not involve an inventive step.